

**REMARKS**

Claims 13-29 are all the claims pending in the application. Claims 13-22 are withdrawn.<sup>1</sup> Claims 23-29 are rejected. Claims 23 and 27 are amended for clarity but without reduction in scope. New claim 30 has been added. Support for the amendment can be found in the original claims and at least at page 4 and Example 12 of the specification. No new matter has been introduced and entry of the amendment is hereby respectfully requested.

**I. Claim Rejections under 35 U.S.C. §, first paragraph**

Claims 23-28 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

**use of the transitional phrase “consisting essentially of”**

On page 4, the Examiner contends that the specification, as filed, does not provide explicit or implicit support for use of the transitional phrase “consisting essentially of”.

In the Examiner’s view, neither Applicant’s specification nor arguments provide evidence of additional components (sequences) which do, or do not, affect the characteristics of the claimed fragment. He reasons further that since the instant 200 base pair sequence is a portion of a larger promoter, it is unclear what additional *relA*/*SpoT* promoter sequences (or other *M. tuberculosis* sequences) would materially change the characteristics of the claimed fragment (*See also* MPEP 2105).

---

<sup>1</sup> On September 5, 2006, Applicant submitted a request for rejoinder of amended-withdrawn claims 13-22, upon allowance of any of elected claims 23-29 to which the Examiner has not yet responding. The Examiner will kindly note for the record that said request is maintained.

Applicant respectfully disagrees with the contention that the specification does not describe additional components (sequences) do not, affect the characteristics of the claimed 200 base pair promoter fragment and submits that, in view of the specification, it is apparent that the claimed fragment is a 200 base pair sequence of SEQ ID NO: 2. SEQ ID NO:2 of the present disclosure is a 266 base pair sequence. One skilled in the art would readily understand that the 66 base pairs not recited in the claims are components which would not materially effect the claimed 200 base pair sequence. Accordingly, use of the phrase “consisting of” would unduly narrow the scope of the claims.

Nonetheless, for purposes of advancing prosecution, a dependent claim that recites “consisting of,” rather than “consisting essentially of” has been added.

**use of the term “adjacent”**

The Examiner states that the specification provides support for a 200 base pair (SEQ ID NO:2) fragment of the promoter of the *relA*/SpoT gene but that claim 23, as presented, reads on a *M. tuberculosis* promoter fragment which is upstream and adjacent to the *relA*/SpoT gene. It is also noted that the specification does not use the term “adjacent” *per se* to describe the relationship between the 200 base pair fragment and the *relA*/SpoT gene that the recitation of “adjacent” broadens the nature of the invention to an extent not supported by the specification. For purposes of advancing prosecution, the term “adjacent” has been replaced with the term “proximal” which is used in the present specification to describe the relationship between the 200 base pair fragment and the *relA*/SpoT.

**claim 23 as amended allegedly contains new matter**

Finally, the Examiner notes that claim 23 recites any 200 base pair promoter fragment upstream and adjacent to the *M. tuberculosis* relA/SpoT gene, while the instant specification provides support only for the 200 base pair sequence of SEQ ID NO:2 and rejects the claim as containing new matter.

Applicant respectfully submits that SEQ ID NO. 2 is a 266 base pair sequence which contains the claimed 200 base pair sequence and when the claims are properly read in light of the specification, it is apparent that the 200 base pair promoter fragment recited in the claims is not any base pair promoter fragment but would be understood to be the 200 base pair promoter fragment contained in SEQ ID NO:2".

Applicant submits further that claim 23 recites not only that the 200 base pair fragment be upstream and "proximal" (as presently amended) to the rel A/SpoT gene, but must also be stable in *M.smegmatis* and *E.coli*. The claim as a whole adequately confines the claimed fragment to the presently disclosed 200 base pair fragment.

**II. Claim rejections under 35 U.S.C. § 102(b)**

Claims 23 and 27 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Fleischmann et al.

On page 7, the Examiner again states that neither Applicant's specification nor arguments provide evidence of additional components (sequences) which do, or do not, affect the characteristics of Applicant's invention and reasons that since the instant 200 base pair sequence is a portion of a larger promoter, it is unclear what additional relA/SpoT promoter sequences (or

other *M. tuberculosis* sequences) would materially change the characteristics of the claimed invention.

As discussed in section I above, Applicant again respectfully notes that SEQ ID NO: 2 of the present disclosures identifies a 200 base pair promoter fragment and components that do not materially affect the claimed promoter fragment. One skilled in the art would understand the present claim language, when read in view of the specification, to cover a specific 200 base pair promoter fragment sequence and components that do not materially affect the recited fragment. Fleischmann fails to teach a *Myobacterium* promoter that consists of the 200 base pair fragment upstream (and proximal) to the *M. tuberculosis* *relA*/*SpoT* gene and thus, Fleischmann does not anticipate the present claims.

**“stability” of the promoter fragment is inherent**

The Examiner does not allege that Fleischmann discloses the stability recitation of claim 23 but states that the stability of the promoter fragment in *E. coli* and *M. smegmatis* appears to be an inherent feature of the *relA*/*SpoT* promoter and rejects claim 27 because it appears to recite an inherent characteristic of the *relA*/*SpoT* promoter recited in claim 23.

Applicant submits that stability has been for to the 200 base pair fragment and is not necessarily an inherent property of the *relA*/*SpoT* promoter.

**III. Claim rejection under 35 U.S.C. § 112, second paragraph**

Claims 23-29 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 and dependent claims are deemed to be vague due to lack of antecedent basis for the phrase "the 200 base pair fragment" Claim 23 has been amended to provide proper antecedent basis.

Claim 27 is deemed vague because the Examiner finds the recitation of a heat shock promoter to be unclear. It is stated that the claim appears to read on any heat shock promoter followed by a specific heat shock promoter in parentheses (P<sub>hsp60</sub>). Claim 27 has been amended to recite "heat shock protein 60 promoter."

Withdrawal of the rejections under 112, second paragraph is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Renita S. Rathinam/

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Renita S. Rathinam  
Registration No. 53, 502

Date: May 30, 2007